

REMARKS

Claims 1–10 are pending in the application. Claims 1–7 were allowed, while claims 8–10 stand rejected under 35 U.S.C. §112, first paragraph.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner rejected claims 8–10 under 35 U.S.C. §112, first paragraph, because the specification while being enabled for treatment of depression, does not reasonably provide enablement for treatment of all other disorders responsive to antagonism of 5-HT₆ receptor. Specifically, the Examiner stated that the "scope of the claims is not adequately enabled...claim language includes diseases that are known and those that are yet to be discovered".

Applicants have deleted claim 8 and amended claims 9 and 10 in accordance with the request of the Examiner, but respectfully disagree that the specification together with the prior art enables the disorders specifically recited in amended claim 9.

In evaluating the enablement question, several factors are to be considered including the specification and all the references as a whole and not just one or two sentences. Applicants have provided biological data in Table 1 for all 35 compounds exemplified in the specific embodiments and demonstrated that all the compounds within the scope of the claims will antagonize the agonist effect of serotonin. The level of skill in the art and predictability in the art is well documented for antagonists of 5-HT receptors and the resulting effects of compounds which modulate the effects of serotonin levels is well-known in the art. Applicants wish to draw the Examiner's attention to page 14, line 32 through page 15, line 1 of the present specification wherein Applicants state that "Clozapine was used as an internal standard for comparison". For the Examiner's information, Clozapine is a drug approved by the FDA as an atypical antipsychotic agent and, consequently, the embodiment

of the present invention should be afforded the same utility without undue experimentation. See also reference AK (Roth, et al., cited in IDS).

In addition, the Examiner quoted statements from three references and the Applicants wish to comment on what each reference fairly teaches "as a whole".

The Examiner highlighted a statement on page 118 of the art reference, Rogers, et al., in which "the relationship between 5-HT₆ receptor antagonism and other neurotransmitter systems is at present unclear". Applicants believe that this sentence is taken out of context since Applicants are not suggesting any utility for other neurotransmitter systems, which are not the subject of any claims in the present application. In fact, the Rodgers, et al. reference supports Applicants' currently amended claims 9. For example, in the abstract on page 114 of the cited reference, Rodgers concludes, "These data indicate that 5-HT₆ receptor antagonism may be involved in cognitive function". The data presented in the reference further supports the statement made on page 118 (sentence prior to Examiner's sentence) which states,

There is increasing evidence that 5-HT systems may be involved in the treatment and pathogenesis of cognitive disorders (Meneses 1998) and cognitive dysfunction is associated with aging and a wide range of neurological and psychiatric disorders.

It is respectfully submitted that the present application is directed to well-known 5-HT systems and not "other neurotransmitter systems".

The Examiner also cited Bentley, et al. and quoted a sentence from the article on page 1541, col. 2, "It is not known, however, whether these effects directly involve an increase in the release of acetylcholine from cholinergic neurons in the rat CNS". Whether the interaction is directly or indirectly is not of concern here. Instead, the Examiner is directed to the very next sentence in which Bentley, et al. states,

Nevertheless, the interaction between the 5-HT₆ receptor and cholinergic neurotransmission is particularly interesting with respect to disease states

such as Alzheimer's disease where there is clear evidence of a cholinergic deficit.

Lastly, the Examiner cites the Cecil Textbook of Medicine (1996) and quotes that there is "no cure for Alzheimer's disease, and no drug tried so far can alter the progress of the disease". Applicants note that this statement was made almost ten years ago. The Physician's Desk Reference (2004) shows four drugs, Aricept, Exelon, Namenda and Reminyl, approved by the FDA for the treatment of Alzheimer's disease.

In view of the foregoing amendments and remarks, Applicants believe that the rejections have been traversed and favorable action on the amended claims is respectfully solicited.

Respectfully submitted,

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Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000

Aldo A. Algieri

Aldo A. Algieri, Ph.D.
Agent for Applicant
Reg. No. 31,697
Telephone: 203-677-6809